UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/014,087	01/27/1998	WENDA C. CARLYLE	1416.25US01	4103

27367 7590 04/05/2006

WESTMAN CHAMPLIN & KELLY, P.A.
SUITE 1400 - INTERNATIONAL CENTRE
900 SECOND AVENUE SOUTH
MINNEAPOLIS, MN 55402-3319

EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/014,087
Filing Date: January 27, 1998
Appellant(s): CARLYLE ET AL.

Hallie A. Finucane
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 19, 2006 appealing from the Office action mailed June 16, 2005.

Appellants included a section labeled "GROUPING OF CLAIMS" that does not comply with the current appeal brief format. Therefore, Appellants are required to provide a corrected copy of the Appeal Brief that does not contain this section and that renumbers the sections therefollowing.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed. Only a request for reconsideration was filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The Appellants' statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

Grounds A to D are correct, but the Appellant failed to mention the provisional obviousness-type double patenting rejection. It is designated as Ground AA as follows:

AA. Whether claims 1, 2, 9, 14, and 21 are unpatentable over claims 1, 8, 10, 13, 15, 34, 35, and 38-40 of copending application number 09/186,810 under the judicially created doctrine of obviousness-type double patenting.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,308,641	CAHALAN	5-1994
EP 0476983	BAYNE et al	3-1992
5,631,011	WADSTROM	5-1997
4,648,881	CARPENTIER et al	3-1987

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 9, 14, and 21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, 10, 13, 15, 34, 35, and 38-40 of copending Application No. 09/186,810. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the copending claims is so similar to the present claimed subject matter that the claim sets read on each other such that they are at least clearly obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States..

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan (US 5,308,641). Cahalan anticipates the claim language wherein the natural

tissue as claimed is the human or animal tissue of Cahalan, and the growth factor as claimed is the biomolecule of Cahalan attached to the tissue where the biomolecule is one of the growth factors listed on column 6, lines 14-18; also see the abstract, column 4, lines 20-43, and column 6, lines 8-28. It is noted that "fixed" and "crosslinked" are synonymous in the tissue graft implant art. Furthermore, glutaraldehyde is disclosed as one of the crosslinking agents of Cahalan; see column 4, lines 58-62. When it contacts the tissue solid surface, it inherently crosslinks it resulting in a crosslinked or fixed tissue as claimed.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayne et al (EP 0476983), or alternatively, under 35 USC 103(a) as being unpatentable over Bayne et al alone.

Bayne anticipates the claim language where the crosslinked natural tissue as claimed is the fixed umbilical cord vein of Bayne. The exogenous polypeptide growth factor as claimed is the VEGF II (i.e. vascular endothelial growth factor) coated onto the tubular support prior to implantation; see the abstract, page 8, lines 14-26, and in particular, page 8, lines 20-23. The Examiner posits that the tubular supports coated with VEGF II include fixed umbilical cord vein, and thus, the claim language is fully met. The attachment of cells to the vessel is done prior to implantation such that the claim language requiring growth factor associated with the tissue is fully met.

Alternatively, if one does not consider the tubular supports coated with VEGF II as including umbilical cord vein, than the claim language is not fully met. However, the Examiner posits that it would have been clearly obvious to use umbilical cord vein as

the tubular support since it is used as an implant in another procedure; it would bring the desired features of tissue properties to the implant site. Furthermore, a combination of proteins, such a fibrin, and growth factor (VEGF II) would have been at least obvious in view of Bayne alone since the teaching of doing the same are all contained in the same paragraph and there is no clear delineation between them.

Claims 1-2, 4-5, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne et al (EP 0476893) in view of Wadstrom (US 5,631,011). Bayne et al discloses an implant having a fibrin coating (a biologic adhesive as claimed), which is applied prior to the VEGF II growth factor (VEGF II is the polypeptide growth factor as claimed). The fixed umbilical cord vein of Bayne et al is the substrate for coating as claimed; see page 8, lines 14-26. However, the Bayne et al cord vein, although a crosslinked human or animal tissue, is not clearly either an allograft or xenograft as claimed. In other words, the tissue of Bayne is generic to both allograft and xenograft tissues. Nonetheless, it is the Examiner's position that it would have been considered clearly obvious to an ordinary artisan to use an allograft or xenograft tissue for the cord vein of Bayne et al absent some showing of criticality therefor.

Wadstrom is cited to show that fibrin is a common biologic tissue adhesive in the art (see the abstract and column 1, lines 1-20), and thus, the fibrin coating of Bayne et al can be called and would function as a biologic adhesive as claimed.

Claims 6-8, 14, 15, 21-24, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne et al and Wadstrom as applied to claims 1-5, 9-11, and 29 above, and further in view of Carpentier (US 4,648,881). Bayne et al fails to disclose

uncrosslinked tissue, the heart valve form of the tissue, or the other tissue types as claimed. However, Carpentier teaches that all uncrosslinked and crosslinked forms of tissue, heart valve tissue forms and other types of tissue are all well known in the art; see column 2, lines 3-15. Hence, it is the Examiner's position that it would have been obvious to use any of these materials as the substrate of Bayne et al for the applications contemplated by Carpentier. One would be motivated to form Bayne et al implants into other shapes in order to make it useful in other sites and broaden its applicability.

(10) Response to Argument

AA. Double Patenting Rejection

Appellants have offered to consider filing a terminal disclaimer if the claims are allowed along with those of copending application 09/186,810.

A. Section 102 Rejection over Cahalan

Appellants argue that Cahalan's disclosure is directed to attaching polyalkylimine to a substrate and not to crosslinking the tissue and attaching an exogenous agent. In response, the Examiner asserts that all the claim limitations are met such that Cahalan's overall purpose for the invention is not relevant. In addition, once Cahalan attaches polyalkylimine to the tissue, it becomes part of the tissue. For this reason, at least the crosslinked polyalkylimine treated tissue is crosslinked, and thus, the claim language is fully met with this interpretation. In fact, the Appellants have admitted that polyalkylimine is lightly crosslinked and it serves as a platform for attachment of a biomolecule; see the paragraph bridging pages 5 and 6 of the Appeal Brief. For this

reason, the Examiner asserts that the substrate of Cahalan clearly constitutes a crosslinked natural tissue to the extent that this language can be given patentable weight.

Furthermore, even if one does not agree that crosslinked polyalkylimine treated tissue constitutes crosslinked tissue as claimed, the Examiner asserts that the crosslinking treatment would also inherently crosslink the tissue protein to some extent. This is due to the fact that the protein of tissue reacts with aldehyde molecules to form crosslinked bonds; see Example 1 of Carpentier et al (US 4,648,881). Finally, the Examiner asserts that the fact that Cahalan is concerned with attaching spacer molecules to a substrate does not mean the disclosure thereof does not inherently anticipate the claim language.

In addition, the Appellants seem to argue that the growth factor of Cahalan is not associated with the tissue. However, the Examiner would like to point out that the term "associated" does not mean bonded or attached in any manner. Rather, it can include materials that are merely next to each other.

B. Section 102/103 rejection over Bayne

Appellants argue that Bayne is directed to growing cells in a medium of VEGF and then plating the cells onto fixed umbilical cord vein; see the paragraph bridging pages 9 and 10 of the Appeal Brief. However, the Examiner asserts that the Appellants have ignored the rest of the paragraph from lines 20 to 26 of page 8. Here, "*tubular supports are coated in vitro with VEGF II prior to implantation into a patient.*" The

Examiner asserts that the "tubular supports" include fixed umbilical cord vein because the fixed umbilical cord vein is also implanted into the patient; see lines 16-19.

If one does not think that "tubular supports" includes fixed umbilical cord vein, then the Examiner asserts that the use of fixed umbilical cord vein is clearly obvious in view of Bayne as a whole.

Nonetheless, since Bayne has all the claim features, as explained in the rejection, the Examiner maintains that the claims are anticipated thereby.

Reading the whole disclosure of Bayne, it is clear that Bayne is quite broad in his application of vascular endothelial cell growth factor II. For example, it is disclosed for use as a medicament (see claim 14), as a treatment for synthetic polymeric vessels (see *supra* and claims 16 and 17), and for use in vascular repair (see claim 17 and page 8, lines 27-37). Clearly, Bayne teaches treatment of a implant with VEGF II prior to implantation and discloses that the implant can be fixed tissue. For these reasons, the Examiner asserts that it would have been at least clearly obvious to use this growth factor on fixed umbilical vein.

C. Section 103 rejection over Bayne and Wadstrom

Appellants argue that Wadstrom does not cure the alleged deficiencies of Bayne because Wadstrom does not disclose a prosthesis of allograft or xenograft tissue having polypeptide growth factor associated therewith; see page 13 lines 1-10 of the Appeal Brief. However, Wadstrom was cited to show that fibrin is considered to be a biological adhesive in the art. One cannot show nonobviousness by attacking references

individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to the argument that allograft and xenograft tissues are all natural tissues, the Examiner has addressed the issue of the tissue source in the rejection. Clearly, the allograft and xenograft encompasses virtually all sources of tissue. For this reason, the use of one or the other would not patentably distinguish the claimed invention from that of Bayne absent some showing of unexpected and unobvious results.

D. Section 103 rejection over Bayne in view of Wadstrom and Carpentier

Appellants basically rely on the arguments made previously that Bayne does not disclose the crosslinked tissue with growth factor. The Examiner respectfully disagrees and asserts that Bayne renders the claimed combination at least clearly obvious. For this reason, the rejection should be maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Paul Prebilic
Primary Examiner
Art Unit 3738

Conferees:

Kevin P. Shaver for Corrine McDermott
Corrine McDermott
Supervisory Patent Examiner
Art Unit 3738

John Calvert
Supervisory Patent Examiner
Art Unit 3765

JOHN J. CALVERT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700